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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,725	05/12/2005	Hidenori Abe	10525.0006	7083
22852 FINNEGAN H	7590 10/02/2007 AN, HENDERSON, FARABOW, GARRETT & DUNNER		EXAMINER	
LLP.			JARRELL, NOBLE E	
	901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413		ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

1	Application No.	Applicant(s)				
	10/534,725	ABE ET AL.				
Office Action Summary	Examiner	Art Unit				
	Noble Jarrell	1624				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period versilized to reply within the set or extended period for reply will, by statute any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 12 M	ay 2005.					
2a) This action is <b>FINAL</b> . 2b) This	This action is <b>FINAL</b> . 2b) This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-20,22,24 and 26-28</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.	C. C. H. H. H. Barrer et land	<b>-</b>				
8) Claim(s) <u>1-20,22,24 and 26-28</u> are subject to r	estriction and/or election requirer	nent.				
Application Papers						
9) The specification is objected to by the Examine	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the						
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C. § 119(a)	)-(d) or (f).				
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau	ս (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list	of the certified copies not receive	ed.				
Attachment(s)	r <del></del> 1					
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail D					
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal F					
Paper No(s)/Mail Date	6)					

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## **DETAILED ACTION**

1. Claims 1-20, 22, 24, and 26-28 are pending in the current application. This is a National Stage of PCT/JP03/14622, filed 11/18/2003, which claims priority to JP2003-76435, filed 03/19/2003, and JP2002-335661, filed 11/19/2002.

## Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20, 22,24, 26-27, drawn to compounds, compositions, and methods of formula (I) where ring A is phenyl, variable B is an alkyl chain with no heteroatoms embedded in the chain, and the group represented by NR<sup>1</sup>R<sup>2</sup> is an amino group that does not form a ring with variables R<sup>1</sup> and R<sup>2</sup>.

Group II, claim(s) 1-20, 22,24, 26-27, drawn to compounds, compositions, and methods of formula (I) where ring A is phenyl, variable B is an alkyl chain with no heteroatoms embedded in the chain, and the group represented by NR<sup>1</sup>R<sup>2</sup> is a pyrrolidine ring.

Group III, claim(s) 1-20, 22,24, 26-27, drawn to compounds, compositions, and methods of formula (I) where ring A is phenyl, variable B is an alkyl chain with no heteroatoms embedded in the chain, and the group represented by NR<sup>1</sup>R<sup>2</sup> is a morpholine ring.

Group IV, claim(s) 1-20, 22,24, 26-27, drawn to compounds, compositions, and methods of formula (I) where ring A is phenyl, variable B is an alkyl chain with no heteroatoms embedded in the chain, and the group represented by NR<sup>1</sup>R<sup>2</sup> is a piperazine ring.

Group V, claim(s) 1-9,11-20, 22,24, 26-27, drawn to compounds, compositions, and methods of formula (I) where ring A is 1,3-thiazoline, variable B is an alkyl chain with no heteroatoms embedded in the chain, and the group represented by NR<sup>1</sup>R<sup>2</sup> is an amino group that does not form a ring with variables R<sup>1</sup> and R<sup>2</sup>.

Group VI, claim(s) 1-20, 22,24, 26-27, drawn to compounds, compositions, and methods of formula I where the combination of variables A, B, and NR<sup>1</sup>R<sup>2</sup> form a 1,2,3,4-tetrahydroisoquinoline ring.

Group VII, claim(s) 1-20, 22,24, 26-27, drawn to compounds, compositions, and methods of formula I where the combination of variables A, B, and NR<sup>1</sup>R<sup>2</sup> form an isoindoline ring

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Group VIII, claim(s) 1-20, 22,24, 26-27, drawn to compounds, compositions, and methods of formula I where the combination of variables A, B, and NR<sup>1</sup>R<sup>2</sup> form a 2,3,4,5-tetrahydro-1H-benzo[d]azepine ring.

Group IX, claim(s) 1-20, 22,24, 26-27, drawn to compounds of formula (I) that are not covered by groups I-VIII.

Group X, claim(s) 28, drawn to compounds encompassed by the structure shown in claim 28.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- (f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.
- (i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
  - (A) All alternatives have a common property or activity; and
  - (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
  - (B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common

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only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables A, B, and the chemical groups represented by NR<sup>1</sup>R<sup>2</sup> result in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:

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=> d que sta
                STR
REP G1=(1-6) A
NODE ATTRIBUTES:
       IS RC
                  AT
DEFAULT MLEVEL IS ATOM
       IS UNS AT
DEFAULT ECLEVEL IS LIMITED
ECOUNT IS E8 C E1 N AT
GRAPH ATTRIBUTES:
RING(S) ARE ISOLATED OR EMBEDDED
NUMBER OF NODES IS 10
STEREO ATTRIBUTES: NONE
L3
              O SEA FILE-REGISTRY SSS SAM L2
                                                               O ANSWERS
 1.8% PROCESSED
                   2000 ITERATIONS
INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)
SEARCH TIME: 00.00.01
FULL FILE PROJECTIONS: ONLINE **INCOMPLETE**
                        BATCH
                                **INCOMPLETE**
                           2186751 TO 2226129
PROJECTED ITERATIONS:
PROJECTED ANSWERS:
                                 O TO
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Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

3. Inventions I-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions each have different combinations of variables A, B, and NR¹R². Even though inventions I-IV have the same ring for A (phenyl), the chemical group that is represented by NR¹R² is distinct and each chemical requires a different search. Invention V is different than every other invention because ring is 1,3-thiazoline. Inventions VI-VII are distinct because they each represent a unique combination of variables A, B, and NR¹R² to form a bicyclic ring. Invention X is different than inventions I-IX because the structure requires a search that is distinct from formula (I) of claim 1. In addition, depending on the presence of certain rings, classification can change. For example piperazine (class 544, subclass 358) is classified differently than pyrrolidine (class 548, subclass 400) and morpholine (class 544, subclass 98). Thus inventions I-X are patentably distinct.

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4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species groups I-X and compounds listed in claim 13. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 28 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Noble Jarrell /NJ/.

JAMES O. WILSON

UPERVISORY PATENT EXAMINER